

Application No.: 10/821,649  
Amendment dated: November 4, 2005  
Reply to Office Action of October 4, 2005  
Attorney Docket No.: 0018.0024.cip (335-144CIP)

b.) Remarks

Claims 18 and 28 have been amended to correct typographical errors. Support for the amendments is found in the specification and originally filed claims. No new matter is being introduced.

Restriction/Election

In response to the Election/Restrictions mailed from the United States Patent Office on October 4, 2005 (Paper No. 20050930) Applicant elects, with traverse, Group III, (Claims 17-28 and 31-33), drawn to a method of treating breast or prostate cancer in a mammal.

Applicant further elects, with traverse, the following species: (a) taxotere; (b) chemotherapeutic drug, and (c) taxotere. In the elected group, claims readable on (b) are 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 31, 32 and 33; claims readable on (c) are 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 31, 32 and 33.

Claims 2-7 and 13-33 are currently pending and stand restricted under 35 U.S.C. §121 into the following three groups as defined in the Office Action:

- I. Claims 2, 16 and 29, drawn to a method of making a medicament for treating breast or prostate cancer, classified in class 424, subclass 278.1.
- II. Claims 3-7, 13-15 and 30, drawn to a composition comprising a chemotherapeutic drug and a low-molecular-weight bile extract, classified in class 424, subclass 528.
- III. Claims 17-28 and 31-33, drawn to a method of treating breast or prostate cancer in a mammal, classified in class 424, subclass 278.1.

Application No.: 10/821,649  
Amendment dated: November 4, 2005  
Reply to Office Action of October 4, 2005  
Attorney Docket No.: 0018.0024.cip (335-144CIP)

The Office Action states that the Groups I and II are related as a process of making and product made, that the product claims are drawn to any chemotherapeutic composition containing the bile extract, while the method claims are drawn to making a product other than those encompassed by the product claims (a method of making a breast cancer or prostate cancer drug).

The Office Action also states that Groups I and III are related as a method of making and a method of using a composition comprising a low-molecular-weight bile extract and that these two methods have different steps which produce different effects, and each method has a different function.

The Office Action further states that Groups II and III are related as product and process of use and that the product can be used to treat a type of cancer other than breast or prostate cancer, as the product may comprise any chemotherapeutic agent and, the product of Group II has uses other than in the method of Group III.

Additionally, the Office Action alleges that the search for any one group differs from the search for any other group, thereby creating an undue burden of search and examination and that the different groups have each acquired a separate status in the art, as shown in part by their different classifications.

Applicant respectfully traverses the above restriction for the following reasons.

Restriction is legally proper when two or more independent and distinct inventions are claimed in one application. 35 U.S.C. § 121. In addition, there must be a serious burden on the Examiner if restriction is required (MPEP § 803). Specifically, MPEP 803 states:

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Applicant respectfully notes that the claims of Groups I-III all relate to a bile-derived composition. Specifically, the method of making a medicament (Group I), the composition (Group II), and the method of treating breast or prostate (Group III), all include the bile-derived composition.

Application No.: 10/821,649  
Amendment dated: November 4, 2005  
Reply to Office Action of October 4, 2005  
Attorney Docket No.: 0018.0024.cip (335-144CIP)

No serious burden is placed on the Examiner in searching and examining the entire application. To perform a thorough search of claims directed to a process of using a product, be it in manufacturing (Group I) or treatment (Group III), or a composition comprising a product (Group II), the product itself must also be searched. Contrary to the position taken by the United States Patent and Trademark Office, searching the non-patent literature requires searching the bile-derived composition discussed above.

Applicant notes that Claims 2, 16 and 29 (Group I), Claims 3-7, 13-15 and 30 (Group II) and Claims 17-28 and 31-33 (Group III) are all classified in the same class (424). Group I and Group III claims also are classified in the same subclass (278.1). No other evidence is presented to indicate a separate status in the art. Thus there is no support for the assertion in the Office Action that the inventions of Group I, II and III have acquired a separate status in the art.

Furthermore, all three groups share the same field of search. Given that all the claims include the bile-derived composition discussed above, it is unlikely that searching a particular group would necessitate a search in an area where no art pertinent to the other two groups would be found.

As set forth in MPEP § 808.02, when the classification is the same and the field of search is the same, "no reasons exist for dividing among related inventions."

Therefore, reconsideration and withdrawal of the Restriction Requirement are respectfully requested.

The Office Action further states that the application contains claims directed to more patentably distinct species, as follows:

- a) one of the chemotherapeutic drugs in claim 4 (the Examiner further alleged that this election will apply to claim 6);
- b) one of the anticancer agents in claim 19 or one of the anticancer agents in claim 20 (the Examiner further alleged that this election will apply to claim 21); and
- c) one of the chemotherapeutic drugs in claim 22.

Application No.: 10/821,649  
Amendment dated: November 4, 2005  
Reply to Office Action of October 4, 2005  
Attorney Docket No.: 0018.0024.cip (335-144CIP)

The USPTO states that Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species in each of a)-c) above for prosecution of the merits to which the claims shall be restricted if no generic claim is finally held allowable. The Office Action indicates that the following claims are generic: claims 3, 5, 18 and 21.

Reconsideration and withdrawal of the election requirement are respectfully requested. Applicant submits that searching the generic claim(s) would place no serious burden on the Examiner. In fact, it might prove less burdensome than conducting search after search, each directed to a different species.

Applicants believe that the present application is ready for examination on the merits. Should any questions arise, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

Houston Eliseeva LLP

By Maria Eliseeva

Maria Eliseeva  
Registration No.: 43,328  
Tel.: 781 863 9991  
Fax: 781 863 9931

Lexington, Massachusetts 02421  
Date: November 4, 2005